AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

1. - 39. (canceled)

40. – 43. (Canceled)

44. (Currently Amended) A ready-for-use sterile, stable, pharmaceutical formulation, in a closed system, comprising an injectable, aqueous solution of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one as its free acid form, ~~crystals~~ free from alkaline residues, ~~from active principle 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-mino-1h-purin-6-(9h)-one as its free acid form, produced by the process described in any one of claims47 to 53, diluted~~ in glucose 5% solution or sodium chloride 0.9% solution, with pH ranging from 3.0 to 6.9, ~~and being~~ packed in a flexible bag ~~manufactured with a tri-laminated material composed by three distinct layers, being an external layer of polyester, an intermediate layer of polyethylene and the inner layer of propylene copolymer~~.

45. (Currently amended) The ~~Pharmaceutical~~ pharmaceutical formulation according to claim 44, in which the solution is a sodium chloride 0.9% solution, and the pH is within the range of 4.5 to 6.9.

46. (Currently amended) The ~~Pharmaceutical~~ pharmaceutical formulation according to claim 44, in which the solution is a glucose 5% solution, and the pH is within the range of 3.2 to 6.5.

47. (Withdrawn) A process of making crystals of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one, free from alkaline residues, comprising:

a) Suspending in a glass reactor coupled with a condenser apparatus 9-((1,3-dixydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one (free base) in demineralized water under stirring until complete homogenization and obtaining of aqueous 9-((1,3-DIXYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE (free base);

b) Elevating the pH to a range between 10.5 and 12.5 by adding an inorganic base under stirring until the total dissolution of all solids;

c) Elevating the temperature of the solution resulting from step (b) to a range between 75° and 90°C;

d) Adding an inorganic or organic acid, thus adjusting the pH into a range from 4.5 to 5.5;

e) Cooling the solution to a temperature ranging from 5° to 7°C and keeping the resulting crystals of 9-((1,3-dinydroxypropan-2-yloxy)methyl)-2-amino-1h-purin- 6-(9h)-one under stirring;

f) Filtering the crystals from resulting from (e) and washing the crystals with an organic solvent selected from the group comprising acetone, ethanol, methanol and isopropanol;

g) Heating and stirring until intensely refluxing, in a glass lined reactor with a reflux condenser, the crystals resulting from step (f) in an organic solvent selected from the group comprising of methanol, ethanol, propanol, isopropanol and butanol, wherein the organic solvent is added in a ratio of 4 to 6 parts in relation to the solid mass of 9-((1,3-dinydroxypropan-2-yloxy)methyl)-2- amino-1h-purin-6-(9h)-one;

h) Cooling the resulting suspension from 1(g) to a temperature ranging from 20° and 30°C, filtering the crystals and drying them under vacuum at temperature ranging from 60° and 80°C, thus obtaining crystals of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin1-6-(9h)-one that are free from alkaline residues.

48. (Withdrawn) The process according to claim 47, in which the inorganic base used in 1(b) is selected from the group consisting of potassium hydroxide, lithium hydroxide and sodium hydroxide.

49. (Withdrawn) The process according to claim 48, in which the inorganic base is sodium hydroxide.

50. (Withdrawn) The process according to claim 47, in which the organic solvent used in steps (f) and (g) is isopropanol.

51. (Withdrawn) The process of claim 47, in which the 9-((1,3-dixydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one (free base) is suspended in the demineralized water in a ratio of 80 to 110 g 9-((1,3-dixydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one (free base) per 0.9 to 1.1 liters demineralized water.

52. (Withdrawn) The process of claim 47, in which the refluxing in step (g) is performed for a time of 3 to 4 hours.

53. (Withdrawn) The process of claim 47, in which 13.5 to 16.5 grams of inorganic base are added in step (b) per 80 to 110 g 9-((1,3-dixydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one (free base) suspended in step (a).

54. (New) A ready-for-use sterile, stable, pharmaceutical formulation, in a closed system, comprising an injectable, aqueous solution in glucose 5% solution or sodium chloride 0.9% solution, with pH ranging from 3.0 to 6.9, of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one prepared by a process comprising:

a) suspending in a glass reactor coupled with a condenser apparatus 9-((1,3-dixydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one (free base) in demineralized water under stirring until complete homogenization and obtaining of aqueous 9-((1,3-DIXYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE (free base);

b) elevating the pH to a range between 10.5 and 12.5 by adding an inorganic base under stirring until the total dissolution of all solids;

c) elevating the temperature of the solution resulting from step (b) to a range between 75° and 90°C;

d) adding an inorganic or organic acid, thus adjusting the pH into a range from 4.5 to 5.5;

e) cooling the solution to a temperature ranging from 5° to 7°C and keeping the resulting crystals of 9-((1,3-dinydroxypropan-2-yloxy)methyl)-2-amino-1h-purin- 6-(9h)-one under stirring;

f) filtering the crystals from resulting from (e) and washing the crystals with an organic solvent selected from the group comprising acetone, ethanol, methanol and isopropanol;

g) heating and stirring until intensely refluxing, in a glass lined reactor with a reflux condenser, the crystals resulting from step (f) in an organic solvent selected from the group comprising of methanol, ethanol, propanol, isopropanol and butanol, wherein the organic solvent is added in a ratio of 4 to 6 parts in relation to the solid mass of 9-((1,3-dinydroxypropan-2-yloxy)methyl)-2- amino-1h-purin-6-(9h)-one;

h) cooling the resulting suspension from 1(g) to a temperature ranging from 20° and 30°C, filtering the crystals and drying them under vacuum at temperature ranging from 60° and 80°C, thus obtaining crystals of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one that are free from alkaline residues;

said solution being packed in a flexible bag.

55. (new) The formulation of claim 44, in which the flexible bag is one comprising a tri-laminated material composed by three distinct layers, being an external layer of polyester, an intermediate layer of polyethylene and the inner layer of propylene copolymer.

56. (new) The formulation of claim 54, in which the flexible bag is one comprising a tri-laminated material composed by three distinct layers, being an external layer of polyester, an intermediate layer of polyethylene and the inner layer of propylene copolymer.